

### **REMARKS**

The Applicants wish to thank the Examiner for his review of the present application. In the present response claims 12, 128 and 173 have been amended, claims 127 and 130 have been cancelled, and claims 185-210 have been added. Claims 1-6, 9-10, 14-55, 106-115, 131-172, and 174 were previously withdrawn and claims 7-8, 11, 56-88, and 100 were previously cancelled. Accordingly, claims 12-13, 89-99, 101-105, 116-126, 128-129, 173 and 185-210 are currently under consideration. No new matter has been added.

### **INTERVIEW SUMMARY**

The Applicants also thank the Examiner for the courtesy of the Interview held on July 1, 2010. The Interview was conducted by phone and was attended by Examiner John Fernando Ramirez on behalf of the Patent Office and by Kathryn Noll, David Cervený, Dr. Daniel Steins, M.D., Ph.D, and Lora Teska, on behalf of the Applicants. During the Interview, the parties discussed the cited references in light of the claimed invention and proposed claim amendments to further distinguish Applicant's invention from the cited art. The Examiner and the Applicants agreed in principal, subject to further search, that inclusion of cortical bone parameters, cortical bone thickness in particular, would distinguish the claims from the cited references. The Examiner and the Applicant's agreed that amendments to the existing claims would be made, based on the discussion. Further, the Applicants requested to file several new claims also based on the discussion, which the Examiner agreed to consider and to potentially accept and examine. The Examiner also stated that he would contact the Applicants, if he considered the new and/or amended claims potentially allowable following an additional search.

### **35 U.S.C. §103**

The office action rejects claims 12, 89-91, 93-99, 101-103, 118-119, 127-130 and 173 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 6,442,287 (Jiang et al., hereinafter "Jiang") in view of U.S. Patent Number 5,915,036 (Grunkin et al.). Claims 127 and 130 have been cancelled.

As amended, claim 12 is directed to a method for analyzing bone comprising obtaining image data of an anatomical structure, locating a region of interest in the image data; generating

a data structure representing a trabecular pattern within the region of interest; performing pixel neighborhood analysis on the at least one data structure; and deriving quantitative data from the results of the pixel neighborhood analysis. Amended claim 12 further requires combining at least two parameters from the group consisting of total area; trabecular perimeter; node count (N); segment count (S); and node-to-free-end segment count (NF).

Jiang does not teach such a method. Rather, Jiang selects two dimensional regions of interest, and performs a background correction within the region of interest, performs a fitting technique, then subtracts the fitted trend from each ROI to yield the trabecular pattern. Jiang then performs a number of calculations in order to determine bone texture characteristics and bone structure. The office action itself admits that Jiang does not explicitly disclose combining at least two parameters from the group consisting of total area, trabecular perimeter, node count (N) segment count (S), and node-to-free-end segment count (NF). Further, Jiang does not perform a neighborhood pixel analysis.

The office action adds Grunkin, et al. to correct the deficiencies of Jiang. Grunkin, however, also does not teach the method of amended claim 12. For example, Grunkin does not teach or suggest combining multiple parameters as disclosed and claimed, namely, total area; trabecular perimeter; node count (N); segment count (S); and node-to-free-end segment count (NF). Instead, Grunkin discloses methods based almost entirely on a single micro-structural parameter, trabecular structure. Grunkin discloses a method of estimating the bone quality of a vertebra using a two-dimensional image (See Grunkin, col. 3, lines 25-30). In particular, Grunkin performs at least one of a variety of background correction techniques and manipulates the two-dimensional image to either enhance prominent features or reduce less dominant features (See Grunkin, col. 4, lines 43-54). Grunkin then extracts information about the trabecular structure from the manipulated image and estimates the bone quality (See Grunkin, col. 4, lines 55-60).

Applicant's method goes beyond this by performing a pixel neighborhood analysis on the structure identified within the trabecular pattern to identify segments, nodes, etc. to gather information on the complexity of the trabecular structure.

Furthermore, there is no legal basis for combining Grunkin with Jiang. There is no stated motivation present in either of the references for combining them. Even if it is assumed to be

true for the sake of argument that Grunkin et al, teach the evaluation of micro-structural, macro-anatomical and biomechanical parameters, as stated in the office action, the unique parameters listed in claim 12 are not listed in either reference. Therefore, the resulting combination could not result in the claimed method for analyzing bone.

Because neither Jiang nor Grunkin discloses locating a region of interest in the image data, extracting a trabecular pattern from the volume of interest, generating a data structure representing the trabecular pattern and deriving quantitative information from the data structure by combining at least two parameters from the group consisting of total area; trabecular perimeter; node count (N); segment count (S); and node-to-free-end segment count (NF), as required by amended claim 12, amended claim 12 is allowable over Jiang and Grunkin.

Furthermore, claims 89-91, 93-99, 101-103, 118-119, 128-129 and 173, which depend from claim 12, are allowable for at least the same reasons.

The office action rejects claims 116-117 and 120-126 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 6,306,822 (Kumagai et al, hereinafter "Kumagai") in view of Jiang, in view of Grunkin.

Claims 116-117 and 120-126 depend from claim 12, but include the additional limitations of administering an agent, and comparing quantitative data to image data taken at different times. Kumagai, however, does not teach such methods. Instead, Kumagai teaches a phosphopeptide and a method of treating bone disease using the phosphopeptide. Nowhere does Kumagai teach or suggest extracting a trabecular pattern from the region of interest and then identifying a data structure representing the trabecular pattern, performing pixel neighborhood analysis and deriving quantitative data from the results as required by claims 116-117 and 120-126.

As dependent claims of amended claim 12, claims 116-117 and 120-126 include the limitations of amended independent claim 12. Therefore, claims 116-117 and 120-126 are allowable over the combination of Jiang and Grunkin for at least the reasons discussed above with regard to amended claim 12.

Accordingly, Kumagai, Jiang and Grunkin fail to teach or suggest, alone or in combination, all of the limitations of claims 116-117 and 120-126, and the claims are therefore allowable over the combination of Kumagai, Jiang and Grunkin.

The office action rejects claims 92 and 104-105 under 35 U.S.C. 103(a) as being unpatentable over Jiang, in further view of Grunkin.

As dependent claims of amended claim 12, claims 92 and 104-105 include the limitations of amended independent claim 12. Therefore, claims 92 and 104-105 are allowable over Jiang and Grunkin, both alone and in combination, for at least the reasons discussed above with regard to amended claim 12.

Accordingly, claims 92 and 104-105 are allowable over the combination of Jiang and Grunkin.

Finally, as discussed during the interview with the Examiner, the cited references do not disclose or suggest, either alone or in combination, the use of a trabecular bone pattern in conjunction with cortical bone parameters, e.g., cortical bone thickness. Thus, newly added claims 185-210, which recite in various forms deriving quantitative data based on these parameters, are neither anticipated nor obvious in light of the references cited by the Examiner.

### CONCLUSION

Applicants submit that the application is now in order for allowance and Applicants respectfully request that a notice of allowance be issued. Applicants believe that a three month extension of time is required and request that the associated fee be charge to deposit account number 19-4972. Applicants also request that any additional fees required by this paper be charged to or any overpayments be credited to deposit account number 19-4972. Applicant also request that the examiner contact applicant's attorney, if it will assist in processing this application through issuance.

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